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VIA E-MAIL & REGULAR U.S. MAIL
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Re: McKesson Matter – Ongoing Settlement Discussions

Dear Geof:

It was a pleasure to meet with you, Don Walker and everyone else last week. The purpose of this letter is to explain my thoughts regarding the information presented during the last two meetings, and to address the impact, if any, the information has had on my view of McKesson's liability.

The information you and Mr. Walker shared with us seemingly supports two points. The first is that following the 2008 investigation and settlement, McKesson implemented a Controlled Substance Monitoring Program ("CSMP") designed to identify suspicious customers, rather than suspicious orders. The other point is that some DEA representatives tacitly endorsed this CSMP. For the following reasons, these two positions have not changed my thinking regarding McKesson's liability under 21 U.S.C. § 842.

I cannot accept that the CSMP implemented by McKesson after the 2008 settlement was designed to identify suspicious customers. It is my informed belief that such a contention is more rationalization than reality. The 2008 Settlement Agreement does not require or implicitly suggest a CSMP focused on suspicious customers. To the contrary, the Settlement Agreement provides that "McKesson shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties." (Emphasis added). The Settlement Agreement further provides as follows:

> "McKesson agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a

> detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1(c). This compliance program shall apply to all current and future McKesson distribution centers registered with the DEA in the United States and its territories and possessions." (Emphasis added).

Moreover, any reasonable analysis of the 2008 Settlement Agreement arrives at the conclusion that its aim was to enhance the Comprehensive Drug Abuse Prevention and Control Act (the "Act") and supporting regulatory scheme, not displace it. It would be grossly inaccurate to suggest the parties to the Settlement Agreement intended to supersede the Act and relevant regulations. McKesson was subject to the Act and regulations generally, and 21 C.F.R. § 1301.74(b) in particular, both before and after the Settlement.

Similarly, the August 12, 2008 Memorandum prepared by Hyman, Phelps & McNamara, P.C. does not promote the notion of a CSMP focused on suspicious customers. Instead, the Memorandum indicates that all parties expected McKesson to report suspicious orders, in compliance with § 1301.74(b). Relevant portions of the Memorandum provide as follows:

> Mr. Walker discussed the order monitoring system and the process for identifying orders that exceed the threshold or that would be deemed suspicious.
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> . . .
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> Mr. Walker discussed how orders are blocked, and that in some cases an order will be reduced, but in other cases an entire order will be blocked. He emphasized, however, that the order will not be filled until an investigation has been completed, whether it be a Level I, II or III. DEA again acknowledged with approval this procedure.
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> Mr. Walker discussed the procedures for filing suspicious orders with the DEA.
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> . . .
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> The IT staff requested a format that would allow the reporting of suspicious orders electronically. We made the point that some reports could be done in this manner if the suspicious order was based primarily on the size or quantity of the order. However, we raised the point that if the suspicious order was based on other factors, information garnered from a site visit would have to be communicated to DEA is some other type of report. (All emphasis added).

Furthermore, all of the versions of the CSMP PowerPoint prepared and presented by McKesson over the years, clearly indicate that the focus of the CSMP was on the order, not the customer. Indeed, the attached slide (from the September 16, 2008 rendering) appears, in one form or another, in every McKesson PowerPoint of which I am aware from July 31, 2008 throug Mr. Walker's presentation last week. In all the materials I have seen, it is a questionable order that should have triggered the three level review process, and it is the order that should have been rendered suspicious if the three level review did not resolve the apparent aberrancy.

In fact, the idea that a distributor would implement a CSMP that concentrates on suspicious customers rather than suspicious orders is contrary to the letter and spirit of those provisions of the Act and regulations aimed at curbing drug diversion. Concentrating on the customer would necessarily allow a number of suspicious orders to get through. After all, a customer cannot be deemed suspicious until a pattern of aberrant orders is developed. Each suspicious order filled risks placing controlled substances in the hands of persons who should not have them. I cannot envision a DEA diversion representative endorsing such an idea, and I have seen nothing indicating that a DEA representative did so.

However, even if one accepts, *arguendo*, that DEA personnel tacitly accepted a CSMP focusing on suspicious customers, the available evidence indicates that McKesson was not following its own program. By its own admission, McKesson reported just 35 suspicious customers between March 2008 and November 2012. According to Mr. Walker, McKesson services approximately 25,000 customers daily. If one assumes that McKesson served the same 25,000 customers every day from 2008 through 2012, then McKesson identified just .14% of its customers as Suspicious. Obviously, this miniscule percentage is inflated, in that McKesson did not have the same 25,000 customers every day from 2008 to through 2012.

What is more telling is that a mere 16 of these suspicious customer reports occurred before July, 15, 2011, the date on which Diversion Investigator Lindsey Malocu requested information about McKesson Landover's top 20 controlled substances customers, and CSMP files for some of them. Of these 16 suspicious customers, just 3 were McKesson Landover customers. In other words, from March 2008 to July 15, 2011, McKesson reported only 3 Landover customers. In total, McKesson reported a scant 8 Landover customers as suspicious from March 2008 to November 2012. Most of these reports came after Diversion Investigator Malocu specifically inquired about the customers in question. If McKesson adopted a CSMP aimed at identifying suspicious customers in 2008, it was not operating properly at the Company's Landover facility.

This conclusion is reinforced by other acts or omissions. Specifically, McKesson has never reported Judy's Drug Store ("JDS") or a JDS order as suspicious. This is remarkable, given the well documented diversion facilitated by JDS. JDS operated a small pharmacy in a very rural West Virginia County, but was ordering inexplicable quantities of Schedule II and III narcotics for an extended period. JDS's orders were being fueled by the clearly suspicious, if not alarming, prescribing patterns of a local physician, Rajan Masih. It is highly improbable that McKesson-Landover was not aware of the problem with JDS and Masih. I have concluded that McKesson did not report suspicions about JDS because the DEA had not inquired about JDS.

Similarly, McKesson never reported Lester & Mowery's ("L&M") or an L&M order as suspicious. ARCOS data reveals that in 2011 McKesson sold 130,500 dosage units of oxycodone to Family Pharmacy Services ("FPS"). In a letter dated April 19, 2012, McKesson informed the DEA that it had ceased sales to FPS and reported that FPS was identified as a suspicious customer based on five findings, which were explained as follows:

> 1. Volume of Purchases. Each of these registrants was purchasing quantities of control substances including specifically Oxycodone, that were larger than other pharmacies of the same size.
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> 2. Purchases of Oxycodone 30mg. In several of the cases we identified purchases of the 30mg dosage unit that were extremely high compared to total oxycodone purchases.
> 3. Cash Sales. It appeared that these pharmacies were dispensing a relatively high percentage of cash sales of Oxycodone.
> 4. Prescribing Physicians. We identified physicians who were the top prescribers at certain of these pharmacies, even though the offices of these individuals were in excess of 50 miles away from the dispensing pharmacy.
> 5. Site Visits. We conducted site visits at each pharmacy to evaluate pharmacy practices in order to determine whether those practices supported the purchase activity. Site visits included discussions with the pharmacists and observations of patient traffic and activity. In these cases, we were not satisfied that the pharmacy operations were consistent with the ordering patterns.

By comparison, McKesson sold 805,000 dosage units of oxycodone to L&M in 2011. In 2009 and 2010, McKesson sales and regulatory compliance personnel relied on claims of increased prescribing by Drs. Lee and Wade and a nurse practitioner named Brown to justify the regular and substantial increases of L&M's thresholds. Apparently, McKesson's personnel weren't paying close attention to what was going on at L&M. Dr. Lee was disciplined by the Commonwealth of Virginia in March of 2010 for continuously prescribing controlled substances to patients without establishing or documenting a treatment plan and without properly monitoring the patients. In July of 2010, Dr. Wade surrendered his DEA registration for cause. Wade was arrested in 2012 and pled guilty to illegal distribution of controlled substances. He is currently serving 70 months in prison. In January of 2012, Brown was arrested by the FBI, and subsequently surrendered his DEA registration for cause. It should also be noted that McKesson-Landover personnel repeatedly misidentified Brown as a physician in documents that were placed in the CSMP file.

It is incomprehensible that McKesson would report FPS as a suspicious customer, while ignoring the circumstances at L&M. This is particularly baffling in light of the fact that FPS and L&M are separated by just 1.8 miles. It is clear that McKesson-Landover was not trying to identify suspicious orders or customers in the case of L&M, or knew the L&M orders were suspicious and did nothing.

In addition, the facts surrounding cessation of sales to FPS and reporting the pharmacy as a suspicious customer confirm that McKesson was not employing a serious CSMP. In 2010 and 2011, McKesson-Landover sold FPS 117,200 and 130,500 dosage units of oxycodone respectively. On February 28, 2012, McKesson ceased sales to FPS because it was determined to be a suspicious customer. At that time, McKesson was in the process of closing the Landover facility and opening the new Ruther Glenn facility. On March 29, 2012, McKesson-Ruther Glenn began selling oxycodone to FPS. During the remainder of 2012, McKesson sold 69,500 units of oxycodone to FPS. In 2013 McKesson-Ruther Glenn sold FPS 120,500 dosage units of oxycodone.

In other words, McKesson-Ruther Glenn picked up where McKesson-Landover left off, even though FPS had been identified as a suspicious customer. McKesson suspended sales to FPS for just one month, even though McKesson reported FPS and notified the DEA that McKesson had ceased sales to the pharmacy. What is more troubling is that McKesson informed the DEA that FPS had been identified as suspicious and that sales to FPS had been suspended in a letter that was sent 21 days after McKesson-Ruther Glenn had resumed sales to FPS.

Mr. Walker and McKesson's management may have intended to implement a meaningful CSMP, and correct the wrongdoing that led to the 2008 settlement. However, this intent was not realized at the Landover distribution facility. I also reject the notion that McKesson's CSMP, as implemented, was endorsed by the DEA. I am not aware of, and you have not offered, evidence of an official DEA approval of McKesson's CSMP. The fact that one or more DEA representatives expressed positive views, in the abstract, of the CSMP framework, does not concern me in the least. Most assuredly, there was never an endorsement of McKesson's implementation of the CSMP.

McKesson's CSMP was not being employed properly at the Landover facility. Consequently, numerous McKesson Landover's customers were able to engage in conduct that led to the diversion of massive quantities of Schedule II and III controlled substances. This must be accounted for in a meaningful way.

The U.S. Attorney's Office remains willing to work towards an amicable resolution of the government's claims under § 842. Towards that end, I will take into consideration all of the information you have provided to us. However, I think it is time to focus on the numbers and finding a pathway to a resolution. I invite you to Wheeling in early April to discuss an outline for resolving our differences over the potential penalty amounts. It is my hope that you will be in a position to discuss the numbers by May.

I appreciate your continuing cooperation in this matter. I look forward to hearing from you.

Very Truly Yours,

WILLIAM J. IHLENFELD, II
UNITED STATES ATTORNEY

By: _____
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AGM/jlc